Research Plan Proposal

Economic Burden of Cancer Treatment on Patients and its Impact on Their Quality of Life

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Introduction

The term Cancer is derived from the Greek word "*karkinos*". The term refers to a non–communicable disease which is characterised by growth of abnormal cells in any part of the human body Rajpal *et al.* (2018). Cancer diagnosis leads to a series of personal health expenditures. It is a disease which lays a huge financial stress on cancer affected households.

There were 14.1 million new cases of Cancer, 8.2 million cancer deaths and 32.6 million people living with cancer (within 5 years of diagnosis) in 2012 worldwide as per Globocan Data (2012). The International Agency for research on cancer GLOBOCAN project has predicted that the cancer burden of India will get doubled in the next 20 years, from approx. 1 million new cases in 2012 to more than 1.7 million cases by 2035. These predictions also indicate that the absolute number of cancer deaths will also rise from about 680000 to 1.2 million in the same period.

Cancer is an important public health and economic issue around the world. An analysis of health care costs in various countries like US, Europe and Canada included only the direct costs incurred by cancer patients like inpatient and outpatient drugs, radiotherapy, diagnostic tests etc. but the indirect costs and other expenditures were not included. There was variation in the costs according to the site of tumours and 1 year survival Agarwal *et al.* (2014). It is a challenge for the healthcare system of developing countries like India to balance the expanding financial burden of cancer on one side, and the increasing incidence and prevalence of many types of cancer on the other side Elkin *et al.* (2010).

Cancer treatment costs represent an appreciable burden for National health System's budget. If the current trend of increasing incidence of disease continues, the cancer care costs will grow further Radavonovic et al. (2011). The incidence of cancer is increasing worldwide, and its management includes huge economic costs which has its adverse effects more on low and middle income countries. A major challenge is to find strategies and their ways of implementation in combating this disease within the limited resources available Das *et al* .(2009).

Cancer disease has profound economic and social consequences for Indian population and it often results in social inequalities. The affected population does not have access to well organised and well regulated cancer care systems in countries like India.

India being a developing nation has limited population who have access to health insurance policies. The cancer burden is varied among different regions within India. India's low rate of public expenditures on health care poses a serious problem. India invest less than 5% of its GDP on central government funded and state funded health care Mallath *et al*.(2014). According to WHO data (2011), the cancer mortality rate in India is 79 per 1 lakh deaths and accounts for over 6% of total deaths.

All the hospitals cannot provide free services to the poor patients as they may not have BPL cards. In Mumbai and Trivandupuram, the tertiary hospitals assess the economic status of patients with the help of social workers and accordingly they decide whether the patient needs free or subsidized treatment but unfortunately this system does not exist in other places Nair *et al*. (2013).

Cancer has an adverse impact not only on the affected individuals and their families but also on the economy of a nation as a whole. Cancer adds on to the vicious cycle of poverty in the demographic regions where resources are limited and health system is fragmented.

Economic burden on cancer patients and their families gets deepened due to the socio-economic inequalities in access to health care and other areas prevalent in the country. If these social inequalities are not addressed, the survival rates are reduced and costs of cancer to individuals are increased Mallath *et al.* (2014). The out of pocket expenditure on treatment of cancer is among the highest of all ailments. It disturbs the family budget and a considerable part of income gets spent on it Mohanti *et al.* (2011).

Previous studies done on cancer treatment costs suggests that 32% households resort to borrowing and contributions for cancer treatment and hospitalization Rajpal *et al.* (2018).

Inequalities in health lead to the requirement of establishment of a new system of health care where people of compromised economic status get benefitted and can attain quality health services. The health policy of a nation must include the questions of cost, availability of health care services and quality in health care.

The health and well-being of people living with cancer diagnosis are of utmost importance and an area of focus. The treatment affects the work life of the patients as well as their earnings and economic well-being Syse *et al.* (2008). Reduction in monthly earnings is usually associated with low living standards. The whole family gets affected when a family member gets cancer. The increase in living expenditure can be due to various factors like travelling expenses, child or elder care, reduced income due to less time etc.

The proposed study will be conducted on a random set of patients and the economic burden of cancer treatment will be evaluated on the patients and their families belonging to different economic group by assessment of direct and indirect costs incurred on treatment. The study will also compare quality of life of the cancer patients and its association with the economic status of patients. The study aims to answer the questions of how the educational status or level of literacy affect the stage of cancer diagnosis and how the different parameters of quality of life are related to economic status. There are some cancers for which poor socio-economic conditions are predisposing risk factors .The estimated cost incurred by cancer patients in receiving anticancer therapy will be provided through this study.

A significant research has been done in assessment of psychosocial distress among cancer patients but little research has been done in the area of economic stress and quality of life (QOL) of the cancer patients Ell *et al.* (2008).

Review of Literature

Jeon , H.S.(2017) examined the long-term effects of cancer on the work status and annual earnings of cancer survivors.

Linkage data combining Canadian 1991 Census microdata with administrative records from the Canadian Cancer Registry, the Vital Statistics Registry and longitudinal personal income tax records was used. Two groups were taken – one of cancer survivors and another is comparison group of patients who were not diagnosed with cancer. Changes in the magnitude of cancer effects during the first 3 years after diagnosis was estimated for the group of cancer survivors diagnosed at ages 25 to 61.

Exact matching and regression models were used to assess with observed and unobserved differences between the cancer and comparison groups. The results show moderate negative cancer effects on work status and annual earnings. Over the 3-year period following the year of the diagnosis, the probability of working is 5 percentage points lower for cancer survivors than for the comparison group, and their earnings are 10 percent lower.

Heinesen, E., et al (2017) studied the association between pre-cancer job dissatisfaction and return-to-work probability 3 years after a cancer diagnosis.

The study was done in Denmark and it included Danish data set – a survey of breast and colon cancer survivors. The survey population included the patients who were diagnosed with breast, colon or melanoma skin cancer in 2006–2008, had an employment 2 years prior to diagnosis and their age at the time of diagnosis was between 30-60 years of age and in 2010 they were alive.

Linear Probability Model was used to find out the marginal effects on return to work probability of explanatory variables. The estimate was done on variables for education, , cancer stage at diagnosis, comorbidity, gender, age, family type, the local unemployment rate and year in which diagnosis was done..

It was found that the return-to-work probability has a negative correlation with pre-cancer job dissatisfaction with mental demands (where the correlation was driven by the high-educated) and with physical demands and the superior (where the correlation was driven by the low-educated).There was no effect on educational gradients in the probability of returning to work after cancer by controlling for pre-cancer job dissatisfaction and pre-cancer ability to work.

DeOliveira, C., et al (2017) estimated and compared the cancer related health care costs in British Columbia and Ontario of Canada from the payers' perspectives.

The objective of this study was to estimate the direct costs in Cancer disease at 21 most common sites from diagnosis to death in British Columbia and Ontario- the two Canadian Provinces. The patients were selected from each provincial cancer registry. Their data on direct costs incurred were analysed on treatment – Chemotherapy and Radiotherapy.

The mean cost of each cancer by phase of care and 95% CI was estimated. The four most common cancers were also examined for costs by resource so as to understand the cost drivers to enable detailed interprovincial comparisons of cost components.

Results showed that overall costs were higher in Ontario. Costs were highest in the initial post-diagnosis and pre-death phases and lowest in the pre-diagnosis and continuing phases, and generally higher for brain cancer and multiple myeloma, and lower for melanoma. Hospitalization was the major cost category. Costs for physician services and diagnostic tests differed the most between provinces. It was concluded that the standardization of data and costing methodology was challenging, but it enabled interprovincial and international comparative costing analyses.

Nielsen, M. (2016) described the socio-economic characteristics, situational factors, pre-loss grief symptoms, depressive symptoms, caregiver burden, and health status in a general population of caregivers of terminally ill patients.

A nationwide population-based cohort study was conducted. Caregivers were systematically recruited through patients registered with drug reimbursement for terminal illness in 2012. Data on socio-economic characteristics was mainly obtained from Danish registries, whereas data on situational factors, distress, and health was measured in questionnaires.

Partners had the highest levels of pre-loss grief and depressive symptoms, while adult children reported the highest levels of caregiver burden. From this cohort, which was estimated to be representative of caregivers to terminally ill relatives in the general population, it was found that high levels of pre-loss grief, depressive symptoms, and/or caregiver burden in one third of all caregivers. These findings call for increased focus on caregivers' need of support.

Yoo C, et al (2016) quantified the burden of hysterectomies between cancer and non-malignant cases undergoing hysterectomy.

The objective of this study was to measure the burden of hysterectomies expressed in Operating Room Time (ORT), Length of Stay (LOS) and Hospitalization Costs and to estimate the incremental effect in cancer patients. U.S. based study; the Premier Perspective® Database containing billing data from over 600 hospitals was used. All elective inpatient hysterectomies (including radical, total and sub-total resections) from 2008-2014 were identified. Resource utilization parameters of ORT, LOS and hospital costs (2014 US

Dollars) were computed from the billing data. Patient's cancer status was identified based on ICD-9 diagnosis codes for uterine, cervical or adnexal cancer.

Patient, procedure, and hospital factors were identified and included in multivariable models evaluating the association of cancer status and resource utilization. It was found that patients undergoing hysterectomy had high economic burden and the resource utilization was significantly higher for patients with a cancer diagnosis.

Chatterton, M., et al (2015) compared the cost-effectiveness of a psychologist-led, individualised cognitive behavioural intervention (PI) to a nurse-led, minimal contact self-management condition for highly distressed cancer patients and carers.

This was an economic evaluation conducted alongside a randomised trial of highly distressed adult cancer patients and carers calling cancer helplines. Services used by participants were measured using a resource use questionnaire, and quality-adjusted life years were measured using the assessment of quality of life – eight-dimension – instrument collected through a computer-assisted telephone interview. The base case analysis stratified participants based on the baseline score on the Brief Symptom Inventory. Incremental cost-effectiveness ratio confidence intervals were calculated with a nonparametric bootstrap to reflect sampling uncertainty.

Results showed no significant differences in overall total costs or quality-adjusted life years (QALYs) between intervention groups. Bootstrapped data suggested that the PI had a higher probability of lower cost and greater QALYs for both carers and patients with high distress at baseline. For patients with low levels of distress at baseline, the PI had a higher probability of greater QALYs but at additional cost. Sensitivity analysis showed the results were robust.

The PI was cost-effective compared with the nurse-led, minimal contact self-management condition for highly distressed cancer patients and carers. More intensive psychological intervention for patients with greater levels of distress appears warranted.

Agarwal A, et al (2014) reviewed the factors which influence the political debate on cancer economics across Europe and North America.

This review was a comprehensive analysis of the literature. It also included the information derived from the interview within each region. The role of health technology assessment is prevalent in informing reimbursement policy and it impacts their ability to ensure access to high value cost effective care. The centre point of cancer economics debate was the provision of drugs and accessibility to radiotherapy and high cost radiation technologies and also challenge in delivering high quality equitable cancer care in existing National Budget. Stagnating health budgets are increasing the complexity of debate.

All the factors were reviewed which were significant in formation of cancer policy including socio-cultural values, advocacy and political influence at the country and regional level. The expenditure and outcomes of cancer care exhibited a significant heterogeneity. The varied views and decisions became challenging and created a significant impact on formation of policy.

The cost of cancer care is an important question all over the world. All countries are trying to achieve equitable availability of therapeutic options in the lieu of available limited resources. The affordability is to be given more importance rather than cultural and political issues in future.

Mahal A, et al (2013) studied the economic burden of cancer on households in India using a large cross-sectional household dataset from India.

The cancer-affected households and their economic outcomes were compared with households with similar socioeconomic and demographic characteristics that do not include a member with cancer. The burden of cancer on households' out-of-pocket health spending, non-medical consumption, workforce participation, and debt and asset sales using data from a nationally representative health and morbidity survey in India for 2004 of nearly 74 thousand households.

Propensity score matching (PSM) was done to compare the outcomes for a household containing a person with cancer to a matched household with no cancer case.

It was found that cancer-affected households experienced higher levels of outpatient visits and hospital admissions and increased out-of-pocket health expenditures per member, relative to controls. Cancer-affected households spent between Indian Rupees (INR) 66 and INR 85 more per member on healthcare over a 15-day reference period, than controls and additional expenditures (per member) incurred on inpatient care by cancer-affected households annually was equivalent to 36% to 44% of annual household expenditures of matched controls..

Cancer-affected households also had significantly higher rates of borrowing and asset sales for financing outpatient care that were 3.3% to 4.0% higher compared to control households; and even higher for inpatient care.

Nair K S, et al (2013) assessed the treatment pattern and expenditure incurred by cancer patients in government tertiary hospitals of Kerala, Maharashtra, Rajasthan, West Bengal and Mizoram.

It was a cross-sectional study of 508 cancer patients from tertiary cancer hospitals of these major cities funded by central/state governments. An in-depth interview scheduled containing questions related to socio-economic and demographic characteristics, cancer related questions was done.

About 45% of the patients used private health facilities as the first point of contact for cancer related diseases as against 32% in public hospitals. About 47% sought private health facilities for cancer investigations, 21% at district/sub-district hospitals, and about 4% contacted primary health care facilities. A majority of the patients (76%) faced financial problems while undergoing treatment.

The results highlight the importance of involving the primary health care system in the cancer prevention activities. Early diagnosis and initiation of appropriate treatment helps in higher survival among patients and reduces costs on treatment.

Mohanti B, et al (2011) did a prospective study to estimate the cost of treatment borne by the cancer patients at an academic tertiary public hospital. The study was done on patients with cancers who received anti- cancer treatment at the All India Institute of Medical Sciences.

The study was done on 432 patients and it measured the economic effects of cancer in 2 phases:- first phase is before coming to the Dr. B. R. A. Institute Rotary Cancer Hospital (IRCH), AIIMS who were not diagnosed at AIIMS. The *second phase* of this study is during a major cancer treatment period at IRCH, AIIMS i.e. radiotherapy treatment which lasts between 5-7 weeks. It was measured in terms of burden on the economic resources of the household as they deal with the disease and its treatment.

All the issues were taken into consideration which indirectly effect financial aspect of cancer patients.

The detailed cost was calculated by weekly collection on 284 patients and it was found that the average economic burden to a cancer patient being treated at AIIMS amounted to Rs.14,031 (before start of radiotherapy) plus Rs. 8184(for a 7 week period of RT course), giving rise to a total expenditure of Rs. 22,215.And when Rs.14,597 was added which the patient spent in first phase before coming to AIIMS, an average cancer patient surveyed in this study would have to bear an economic burden of Rs.36,812 for the entire cancer therapy.

Chusteck Z (2010) quantified economic loss due to cancer and other diseases on a global basis. As per report from American Cancer Society, cancer has a greater economic impact from premature death and disability than all causes of death worldwide.

The report used WHO computations to determine disability-adjusted life-years (DALY), which combine the years of life lost by premature death and the years lived with a disability resulting from the disease. In addition, the economic value of a year of healthy life was calculated using a method employed by the WHO Commission on Macroeconomics and Health, which takes into account GDP.

The author estimated that the total economic impact of premature death and disability from cancer worldwide was $895,000 million in 2008. The top three types of cancers that had the

greatest economic impact globally were lung cancer ($188,000 million), colorectal cancer ($99,000 million), and breast cancer ($88,000 million).

These distributions vary somewhat among different countries, When the impact was calculated for the different regions of the world, according to both DALYs lost and economic value lost, the cancers with the greatest impact were lung, colorectal, and breast cancers in high-income and upper-middle-income countries; lung, stomach, and liver cancers in lower-middle-income countries; and mouth/oropharyngeal, cervical/uterine, and breast cancers in low-income countries.

Lamberts Q, et al (2008) compared the cost effectiveness of different screening tools used in breast cancer.

Life histories of breast cancer patients were modelled as a Markov process using the Dutch MISCAN (Micro simulation Screening Analysis) model. A lower cumulative incidence and delayed diagnosis based on Indian data was incorporated into the model. The model was used to estimate the costs of screening for breast cancer in India, its effects on mortality, and its cost-effectiveness (i.e., costs of screening per life-year gained or life saved). Screening using clinical breast examination (CBE) or mammography among different age groups and at various frequencies was analyzed. Costs were expressed in international dollars (Int. $), the currency used by the World Health Organization. Sensitivity analyses were performed to determine which factors influenced cost-effectiveness.

The Clinical Breast examination on age group 40-60 years was predicted to be nearly as efficacious as biennial mammography screening for reducing breast cancer mortality while incurring only half the net costs. It was concluded that the estimated cost-effectiveness of CBE screening for breast cancer in India compares favourably with of mammography in developed countries.

Chirikos TN, et al (2001) emphasised on the measurement of costs of treatment, the variability of cost/outcome ratios, and the analysis of the factors that predicted or explained this observed variation.

Economic analysis is characterized by a simultaneous consideration of treatment costs and outcomes; it focuses on how treatment cost/outcome ratios vary across patient populations with similar diseases. Oncology managers need information about variations in treatment costs across cancer patients in different regions so the economic aspects of cancer treatment were investigated. The analysis was related to lung and breast cancer patients. The conclusion was that economic analysis of cancer treatment costs is feasible and that it can provide useful data for managerial decision making.

Portenoy R (1995) found that the costs associated with the provision of optimal analgesic therapies vary enormously with the site of care.

Economic analysis of cancer pain management was affected by the lacunae in systematic outcomes research. An economic analyses of cancer pain management should provide the justification for the costs of optimal care, and recognition of the link between cancer pain and palliative care.

Reimbursement contingencies also influence the delivery of optimal care. It was concluded that the costs associated with the provision of optimal analgesic therapies vary enormously with the site of care. The ability to reduce pain-related hospitalizations might be a valid and easily measured indicator of a cost-saving therapy.

The need for cancer pain management and palliative care undoubtedly contributed to the extremely high costs that may devolve to families of patients with cancer. This burden got huge in the form of direct out-of-pocket expenses or lost income from the need to care for the patient. The author suggested that there was a need for further research to determine the impact of these costs on access to care, effectiveness of medical treatments, and the quality of life of the patient and family.

Stommel M, Charles W, Barbara A. (1993) found that the costs borne by the family of cancer patient for duration of 3 months period is almost same as the cost incurred in a nursing home for the same period.

The major component of indirect costs was required to be included to get a wider picture of home care costs. Data was collected from a sample of 192 patients with cancer and their families in Lower Michigan. The costs included the indirect costs also; they computed family labor in terms of monetary values for the time spent caring for the patient with cancer. The assigned monetary cost either was equated with income losses of the care giver or was based on a putative market value of the expended labor time.

Out-of-pocket expenditures examined in this study covered all cancer care-related expenses for which the patient was not reimbursed by third parties. The author concluded that when family labour was included in the cost calculations, average cancer home care costs for a 3-month period were not much lower than the costs of nursing home care. The substantial variation in home care costs was not related to the type of cancer diagnosis, type of treatment, or time since diagnosis. It was related to the functional status of the patient and the family living arrangements.

Relevance of Study

As far as the review of literature is concerned, no such study in context to Rajasthan is found. The outcomes of this study will help in bringing some modification and innovations in health care policies of Rajasthan. Aailability of financial resources can be explored and efforts could be made to improve the quality of life of lower socio-economic group by some additional measures and efforts.

Objectives of the Study

1. To assess the economic burden on cancer patients undergoing treatment.

2. To assess the impact of cancer treatment on quality of life of patients of different socio-economic strata.

Hypotheses

1. The first hypothesis is –

Null Hypothesis

H_0: There is no adverse impact of cancer treatment on the economic conditions of patients.

Alternate Hypothesis

H_1: The cancer treatment has an adverse impact of cancer treatment on the economic conditions of patients.

2. The second hypothesis is –

Null Hypothesis

H_0: There is no significant difference between the quality of life of patients of higher socio-economic group and lower socio-economic group.

Alternate Hypothesis

$H_{1:}$ There is significant difference between the quality of life of patients of higher socio-economic group and lower socio-economic group.

Methodology

The study attempts to analyse the economic burden on cancer patients and their families.

The present study is a prospective study and it will be carried out for a period of 1 year approx.; it will include both primary data and secondary data. The primary data will be collected through interview method at first point of contact at OPD Counter. The patients will be asked about their social status, financial status, literacy level, particulars of household, age, sex and income through a well-structured interview schedule. The patients will also be asked about details of the daily activities of life, to measure quality of life, through a questionnaire and then its association with their economic status can be assessed.

The quality of life is measured through a validated questionnaire which broadly asks the questions about fatigue, daily activities, breathing, food habits, financial issues etc. and then scoring can be done. The most common aspects included in quality of life indicators address physical symptoms such as nausea, vomiting, fatigue; tiredness and pain; hair loss; functional ability; sexuality, intimacy, and body perception; emotional symptoms such as worry, anxiety, depression, and insecurity, social function, work life, family situation, hope for the future, future planning; spiritual aspects and financial burden. The total quality of life assessment, i.e. general life satisfaction is measured according to the scoring criterion and comparison in different economic groups can be made.

The study will be conducted on the patients in Bhagwan Mahaveer Cancer Hospital and Research Centre Jaipur which is a tertiary hospital. The institute Bhagwan Mahaveer Cancer Hospital and Research Centre is a trust organisation so it has facilities for BPL patients, category patients and patients from higher economic class also, so that a heterogeneous sample can be obtained. It will enable us to do survey across different economic status.

The number of patients which will be interviewed for basic details will be approximately 300 but the assessment of economic burden and quality of life will be done on 200 patients. The 100 patients will be interviewed extra because non-response, treatment failure, non compliance to treatment, deaths etc. are expected.

The hospital segregates patients broadly in 2 groups: BPL and Non-BPL patients. The patients will be selected via systematic sampling from 2 groups using proportional allocation.

The patients after interviewing will be further divided into 3 groups- low income, middle-income and high income groups. The quality of life assessment will be done twice on all the patients from 3 groups - first at the start of treatment and second after 6 months of treatment.

The change in quality of life at 2 points between 3 groups will be evaluated using Chi square test .

The study will capture the treatment costs and major out-of-pocket expenditures made by the patient/household during cancer treatment- i.e. medicines, tests, transport to and from hospital, accommodation, and food. The cost of treatment and the costs incurred by cancer patients on daily basis apart from treatment will be added and then this calculated cost will be compared with monthly income of the patient. This data will be used to estimate the economic burden on patients and their families. Since cancer is a major disease which not only demands huge treatment costs but indirect costs also. It ruins a person physically as well as financially.

Tools used in the analysis of data:-

Mean, Standard Deviation and Percentage will be used to describe the general characteristics of the study sample. Chi Square Test will be used to test the hypothesis framed in the study. The socio economic status of cancer population can be evaluated in terms of education, occupation and income by using charts and diagrams.

Chapter Scheme (Tentative)

The proposed study will be organized in the following chapters:

1. Introduction:

Cancer –its impact on Life .

Research gap and relevance of study

Objectives of the Study

Hypotheses

Methodology

2. Review of Literature

3. Cancer- Overview in world

   Cancer –Overview in India

4. Economic Burden of Cancer

5. Quality Of Life of Cancer Patients

6. Conclusions and Discussion

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